Application Number: 10/508,739

Amendment Dated: December 4, 2008

Response to Office Action dated July 15, 2008

## Amendments to the Claims:

This listing of claims will replace all prior versions, and listings, of claims in the application:

1. (Currently amended) A method for preparing an assembly for delivering a degradable and bioresorbable polymeric stent that is substantially resistant to negative recoil when expanded mechanically to a final predetermined diameter in a lumen of a tube, duct, or vessel of a mammalian subject, the method comprising the following steps in order:

heating a polymeric cylindrical device which is at a final predetermined diameter (a) and wall thickness to a temperature sufficiently above the glass transition temperature (Tg) of the polymer and for a time sufficient to erase memory of previous processing of the polymeric cylindrical device,

wherein the final predetermined diameter and wall thickness are substantially the same as the diameter and wall thickness of a stent that has been expanded to a final desired diameter at a target site in a tube, duct, or vessel of the mammalian subject,

wherein the device is mounted on a solid support for maintaining the cylindrical device at the final predetermined diameter, and

wherein the polymeric cylindrical device has a wall defining a first open end, a second open end, and a channel connecting the first and the second open end;

- (b) rapidly cooling the polymeric cylindrical device at a temperature below the Tg of the polymer to guench the polymeric cylindrical device and to provide an educated polymeric cylindrical device having a memory of the final predetermined diameter;
- forming slits, voids, or open spaces in the wall of the polymeric cylindrical device (c) prior to step (a) or after step (b), wherein the slits, voids, or open spaces are configured to allow a reduction in the diameter of the device without substantially altering the wall thickness of the device;
- mounting the educated polymeric cylindrical device on an inflatable balloon (d) catheter;
- reducing the diameter of the cylindrical device by heating the cylindrical device to (e) a temperature at or slightly above the Tg of the polymer while evenly applying pressure on the exterior surface of the wall of the cylindrical device; and

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(f) then rapidly cooling the cylindrical device below the Tg of the polymer to provide an assembly comprising a inflatable balloon catheter and an expandable polymeric stent which is substantially resistant to negative recoil when expanded mechanically to the final predetermined diameter by inflation of the balloon in the lumen of a tube, duct, or vessel of the mammalian subject or when expanded mechanically to the final predetermined diameter by inflation of the balloon and stored at 37° C for 4 to 6 weeks or more.

## 2. (Canceled)

- 3. (Previously presented) The method of claim 1 wherein the device is formed from a polymer having a Tg of 45°C or greater.
- 4. (Currently amended) The method of claim 1 wherein the cylindrical device is formed from a polymer having a Tg greater than 57°C from about 45 °C to about 120 °C.
- 5. (original) The method of claim 1 wherein the wall thickness of the cylindrical device is substantially the same before and after step (e).
- 6. (Previously presented) A method for preparing an assembly for delivering a degradable and bioresorbable polymeric stent into the lumen of a tube, duct, or vessel of a mammalian subject, the method comprising the following steps in order:
- (a) providing a polymeric cylindrical device formed from a polymer having a Tg of at least 45°C and comprising a wall defining a first open end, a second open end, and a channel connecting said first open end and said second open end, wherein the cylindrical device is at a final predetermined diameter and wall thickness, the final predetermined diameter and wall thickness being comparable to the final desired diameter and wall thickness of a stent following expansion at a target site in a tube, duct, or vessel of a mammalian subject
- (b) educating the device by erasing memory of previous processing of the polymeric device and establishing a memory of the final predetermined diameter; wherein such education is

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achieved by heating the device to a temperature at least 8°C above the Tg of the polymer while said device is mounted on a solid support;

- (c) quenching the device to provide an educated polymeric cylindrical device having a memory of the final predetermined\_diameter;
- (d) forming slits, voids, or open spaces in the wall of the polymeric cylindrical device before or after the device is educated;
- (e) mounting the educated polymeric cylindrical device on an inflatable balloon catheter;
- (f) crimping the cylindrical device on the inflatable balloon catheter while heating the cylindrical device to a temperature at or slightly above the Tg of the polymer; and
- (g) then rapidly cooling the cylindrical device below the Tg of the polymer to provide an assembly comprising an inflatable balloon catheter and an expandable polymeric stent which is substantially resistant to negative recoil when expanded mechanically to the final predetermined diameter in the lumen of a tube, duct, or vessel of a mammalian subject or when expanded mechanically to the final predetermined diameter and stored at 37°C for 4 weeks or more.
- 7. (Currently amended) A method for preparing an assembly for delivering a degradable and bioresorbable polymeric stent into the lumen of a tube, duct, or vessel of a mammalian subject, the method comprising the following steps in order:
- (a) providing a hollow, polymeric cylindrical device comprising a wall having slits, openings, or voids therein, wherein the hollow cylindrical device has a radial diameter that is less than the final predetermined diameter of the stent, the final predetermined diameter being the desired diameter of the stent following expansion at target site in a tube, duct, or vessel of a mammalian subject;
- (b) heating the polymeric cylindrical device to a temperature close to or above the Tg of the polymer while expanding the device to the final predetermined diameter;
- (c) mounting the expanded cylindrical device on a solid support for maintaining the cylindrical device at the final predetermined diameter;

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- (d) heating the mounted cylindrical device to a temperature sufficiently above the glass transition temperature (Tg) of the polymer and for a time sufficient to erase memory of previous processing of the polymeric device;
- (e) rapidly cooling the mounted cylindrical device at a temperature below the Tg of the polymer to quench the polymeric cylindrical device and to provide an educated polymeric cylindrical device having a memory of the final predetermined diameter;
- (f) mounting the educated polymeric cylindrical device on an inflatable balloon catheter;
- (g) reducing the diameter of the cylindrical device by heating the cylindrical device to a temperature at or slightly above the Tg of the polymer while evenly applying pressure on the exterior surface of the wall of the cylindrical device; and
- (h) then rapidly cooling the cylindrical device below the Tg of the polymer to provide an assembly comprising a inflatable balloon catheter and an expandable polymeric stent which is substantially resistant to negative recoil when expanded mechanically to the final predetermined diameter by inflation of the balloon in the lumen of a tube, duct, or vessel of the mammalian subject or when expanded mechanically to the final predetermined diameter by inflation of the balloon and stored at 37° C for 4 to 6 weeks or more
- 8. (Previously presented) The method of claim 6 wherein the device is formed from a polymer selected from PLA and stereocopolymers (copolymers composed of L and D units), PLAGA, Poly(lactic-co-glycolic-co-gluconic acid.
- 9. (Currently amended) The method of claim 6 wherein the stent is formed from a polymer having a Tg of 45 °C or greater from about 45 °C to about 120 °C.
- 10. (Previously presented) A method for preparing an assembly for delivering a degradable and bioresorbable polymeric stent into the lumen of a tube, duct, or vessel of a mammalian subject, the method comprising the following steps in order:
- (a) providing a polymeric cylindrical device formed from a polymer having a Tg of at least 45 °C and comprising a wall defining a first open end, a second open end, and a channel

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connecting said first open end and said second open end, and having slits, voids, or open spaces for permitting expansion and contraction of the device without substantially altering the thickness of the wall, wherein the cylindrical device has a radial diameter that is less than the final predetermined diameter of the stent, the final predetermined diameter being the desired diameter of the stent following expansion at a target site in a tube, duct, or blood vessel of a mammalian subject;

- (b) expanding the polymeric device to the final predetermined diameter while heating to a temperature close to or above the Tg of the polymer;
- (c) educating the device by erasing memory of previous processing of the polymeric device and establishing a memory of the final predetermined diameter; wherein such education is achieved by heating the device, which is mounted on a support, to a temperature at least 8°C above the Tg of the polymer;
- (c) quenching the device to provide an educated polymeric cylindrical device having a memory of the final predetermined desired diameter;
- (d) mounting the educated polymeric cylindrical device on an inflatable balloon catheter;
- (e) crimping the cylindrical device on the inflatable balloon catheter while heating the cylindrical device to a temperature at or slightly above the Tg of the polymer; and
- (f) then rapidly cooling the cylindrical device below the Tg of the polymer to provide an assembly comprising an inflatable balloon catheter and an expandable polymeric stent which is substantially resistant to negative recoil when mechanically expanded by inflation of the balloon to the final predetermined diameter and implanted in the lumen of a tube, duct, or vessel of a mammalian subject or when mechanically expanded by inflation of the balloon to the final predetermined diameter and stored at 37°C for 4 weeks or more.

## 11-18. (Canceled)

19. (Previously presented) A method for preparing a degradable and bioresorbable polymeric stent that is substantially resistant to negative recoil when expanded mechanically to a final predetermined diameter in a lumen of a tube, duct, or vessel of a mammalian subject, the

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method being performed before the stent is mounted on a balloon catheter and comprising the following steps in order:

(a) heating a polymeric cylindrical device which is at the final predetermined diameter of the expanded stent to a temperature sufficiently above the glass transition temperature (Tg) of the polymer and for a time sufficient to erase memory of previous processing of the polymeric device,

wherein the polymeric cylindrical device has a wall defining a first open end, a second open end, and a channel connecting the first and the second open end; and

wherein the device is mounted on a solid support for maintaining the cylindrical device at the final predetermined diameter;

- (b) rapidly cooling the polymeric cylindrical device at a temperature below the Tg of the polymer to quench the polymeric cylindrical device and to provide an educated polymeric cylindrical device having a memory of the final predetermined diameter; and
- (c) forming slits, voids, or open spaces in the wall of the polymeric cylindrical device prior to step (a) or after step (b), to provide a stent that is substantially resistant to negative recoil when mechanically expanded to the final predetermined diameter by inflation of a balloon that has been inserted into the channel of the polymeric device and implanted in the lumen of a tube, duct, or vessel of a mammalian subject or stored at 37°C for 4 weeks or more.
- 20. (Previously presented) The method of claim 19 wherein the cylindrical device is formed from a polymer having a Tg of at least 45°C.
- 21. (Previously presented) The method of claim 19 wherein the device is formed from a polymer selected from PLA and stereocopolymers (copolymers composed of L and D units), PLAGA, Poly(lactic-co-glycolic-co-gluconic acid.
- 22. (Previously presented) A method for preparing a degradable and bioresorbable

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polymeric stent that is substantially resistant to negative recoil when expanded mechanically to a final predetermined diameter and implanted into the lumen of a tube, duct, or vessel of a mammalian subject or when expanded mechanically to a final predetermined diameter and stored at 37°C for 4 weeks or more, the method being performed before the stent is mounted on a

balloon catheter and comprising the following steps in order:

(a) providing a hollow, polymeric cylindrical device comprising a wall having slits, openings, or

voids therein, wherein the hollow cylindrical device has a radial diameter that is less than the

final predetermined diameter of the stent, and wherein the polymeric device has a Tg of 45°C or

greater;

(b) heating the polymeric cylindrical device to a temperature close to or above the Tg of the

polymer while expanding the tube to a diameter that is equal to or slightly greater than the final

predetermined diameter;

(c) mounting the expanded cylindrical device on a support for maintaining the cylindrical device

at the final predetermined diameter;

(d) heating the mounted cylindrical device to a temperature sufficiently above the glass transition

temperature (Tg) of the polymer and for a time sufficient to erase memory of previous

processing of the polymeric device; and

(e) rapidly cooling the polymeric cylindrical device at a temperature below the Tg of the polymer

to quench the polymeric cylindrical device and to provide an educated polymeric cylindrical

device that is substantially resistant to negative recoil when mechanically expanded to the final

predetermined diameter by inflation of a balloon that has been inserted into a channel in the

cylindrical device and implanted in the lumen of a tube, duct, or vessel of a mammalian subject

or stored at 37°C for 4 weeks or more.

23. (Previously presented)

The method of claim 22 wherein the device is formed from a

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polymer selected from PLA and stereocopolymers (copolymers composed of L and D units), PLAGA, Poly(lactic-co-glycolic-co-gluconic acid.

## 24-26 (Canceled)

- 27. (Previously presented) The method of claim 1, wherein the polymeric device is formed from PLA.
- 28. (Previously presented) The method of claim 6, wherein the polymeric device is formed from PLA.
- 29. (Previously presented) The method of claim 7, wherein the polymeric device is formed from PLA.
- 30. (Previously presented) The method of claim 10, wherein the polymeric device is formed from PLA.
- 31. (Previously presented) The method of claim 19, wherein the polymeric device is formed from PLA.
- 32. (Previously presented) The method of claim 22, wherein the polymeric device is formed from PLA.
- 33. (Previously presented) The method of claim 1, wherein the method provides an expandable polymeric stent that exhibits positive recoil when said stent is not fully expanded mechanically to the final predetermined diameter.
- 34. (Previously presented) The method of claim 6, wherein the method provides an expandable polymeric stent that exhibits positive recoil when said stent is not fully expanded mechanically to the final predetermined diameter.

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35. (Previously presented) The method of claim 7, wherein the method provides an expandable polymeric stent that exhibits positive recoil when said stent is not fully expanded mechanically to the final predetermined diameter.

36. (Previously presented) The method of claim 10, wherein the method provides an expandable polymeric stent that exhibits positive recoil when said stent is not fully expanded mechanically to the final predetermined radial diameter.